

Pharmacy Take-Back Programs

Opportunities for Congress, Liabilities for Pharmacies

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The introduction of new federal legislation that could require pharmacies to dispose of unused or outdated prescriptions highlights a growing concern about “rogue” drugs that are both circulating outside the conventional distribution system and being dumped in bodies of water. Two federal organizations, the Drug Enforcement Administration (DEA) and the Environmental Protection Agency (EPA), had each begun regulatory proceedings on the public health and environmental impact of prescription drugs. The concerns are that consumers might flush unused prescription drugs down the toilet or leave them lying around in the medicine cabinet for unsuspecting children or others to filch. In nursing homes and hospitals, medications often pile up in accessible storage cabinets, where they, too, tend to disappear. In any of these instances, as with the proposed legislation, pharmacies could be in line for new responsibilities that might or might not come with federal funding attached.

Although the public health and environmental problems are distinct from each other, they are also linked in some respects. Long-term-care (LTC) facilities and consumers cannot return expired or unused medications, even controlled substances, to pharmacies. In a few localities, local law enforcement agencies take back and dispose of controlled substances. A small number of pharmacies accept general prescription drugs, according to local ordinances and state Boards of Pharmacy, and pass them on to “reverse distributors,” who dispose of them. Generally, however, pharmacies today rarely serve as a take-back point for individuals and institutions. That could change, though.

We all know that lots of expired and unused pills are floating around. In April 2009, the North Carolina Bureau of Investigations, in conjunction with the state’s local sheriffs’ offices, undertook “Operation Pill Crusher.” This effort netted 144,000 doses of unwanted prescription medications.

The DEA is concerned with the portion of unwanted drugs that consist of controlled substances. Many of these drugs, which accumulate at LTC facilities, tend to disappear into the black market. Controlled substances, as well as other drugs, can also disappear from the family medicine cabinet; this is apparently a growing problem, according to the DEA, because teenagers view them as safer than heroin, methamphetamines, and cocaine. These agents are also easier to obtain.

In both instances, the opportunities for safe disposal of outdated or unused drugs are limited. The DEA has some suggestions for getting pharmacies involved, perhaps through take-back programs, which are currently regulated only through law enforcement agencies.

Even though old, unused controlled substances constitute only 10% of all prescription drugs in the distribution system, they cause environmental problems when they’re flushed down the toilet at home or at an institution. The environmental threat to lakes, streams, and rivers from discarded pharmaceuticals of all stripes is also a growing concern, which the EPA is starting to address. The EPA also sees pharmacy take-back programs as one of several potential solutions.

The EPA has proposed a rule that would allow all types of pharmaceuticals to be treated as “universal” waste, which would make it easier for LTC facilities and pharmacies to dispose of old stock in an environmentally safe way. The DEA is considering whether to change current laws so that individuals, LTC facilities, and others can return outdated controlled substances to their pharmacies.

With these DEA and EPA potential actions percolating in the background, the

House Judiciary Committee held hearings this summer to get views on two new bills from the Obama administration, public health groups, and the pharmacy industry. These bills are parallel in concept but divergent in implementation.

The Secure and Responsible Drug Disposal Act (H.R. 1359) and the Safe Drug Disposal Act (H.R. 1191) basically focus on the DEA concerns, such as the diversion of controlled substances; however, the bills offer different remedies. H.R. 1359 basically gives the DEA additional authority under current law to prescribe new options, such as allowing LTC facilities to funnel old controlled substances back to the pharmacy that filled the prescription. That pharmacy would then dispose of the drugs.

H.R. 1191 bypasses the DEA; instead, it would permit states to set up model programs to deal with a potential diversion of controlled substances. Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control at the DEA, says that the Obama administration supports H.R. 1359 but not H.R. 1191.

With regard to take-back programs, whether stimulated by the DEA, EPA, or H.R. 1359, the National Community Pharmacists Association (NCPA) is lukewarm at best. The NCPA worries that costs would be imposed on pharmacies for which federal funding would not be forthcoming. The American Pharmaceutical Association (APhA) says it “would not support any mandated take-back program that would create additional costs to pharmacy.”

A second cause of concern relates to a possible new source of legal liability that arises from take-back programs, whether they involve controlled substances or prescription drugs more broadly.

Both concerns are significant, of course. Although the legislation is in its infancy and the regulatory proceedings are moving slowly, ostensibly low-profile issues can be transformed from tortoises to hares very quickly, when no one is paying attention. ■

